UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: Nexium (Esomeprazole Magnesium) Antitrust Litigation This Document Relates to: *Walgreen* (No. 13-cv-10337-WGY) *Giant Eagle* (No. 13-cv-11305-WGY) *Rite Aid* (No. 13-cv-12074-WGY)	MDL No. 2409 Civil Action No. 1:12-md-02409-WGY

RETAILER PLAINTIFFS' MEMORANDUM IN
OPPOSITION TO TEVA'S MOTION FOR SUMMARY JUDGMENT

Plaintiffs in the *Walgreen*, *Giant Eagle* and *Rite Aid* cases respectfully submit this memorandum in opposition to Teva Pharmaceuticals USA, Inc.'s and Teva Pharmaceutical Industries, Ltd.'s motion for summary judgment (Docs. 600 & 601). The motion should be denied.

INTRODUCTION

Teva argues in its motion that it cannot be liable for entering into a reverse-payment agreement with AstraZeneca under *Federal Trade Comm'n v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), because the only "payment" it received was the effective forgiveness of Teva's liability to AstraZeneca on infringing sales of a separate generic drug (Prilosec) and Plaintiffs have not shown that the settlement was a "sham." This is a misreading of *Actavis* and a misunderstanding of Teva's burden on summary judgment.

First, while *Actavis* permits entry-date settlements of Hatch-Waxman litigation that do *not* include a payment, and also permits traditional compromises of post-marketing patent infringement damages claims, there is nothing in *Actavis* which suggests that a highly favorable

settlement of an unrelated claim for patent infringement damages cannot amount to a payment from the patent holder to the generic competitor when included in an entry-date Hatch-Waxman settlement. And second, the relevant issue under *Actavis* is not whether the settlement was a "sham," but simply whether it represents a payment from the patent holder to its competitor. There is evidence in the record from which a reasonable, properly instructed jury could find that Teva did receive a payment, and so Teva's motion must be denied.

ARGUMENT

I. Teva Was Paid For Delay

As the Supreme Court recognized in *Actavis*, reverse-payment settlements of Hatch-Waxman patent litigation are subject to scrutiny under the rule of reason because they can operate as a means "to maintain and to share patent-generated monopoly profits." 133 S. Ct. at 2237. In this case, Teva entered into an agreement to delay the launch of its generic Nexium product until May 27, 2014 and, in return, AstraZeneca effectively forgave Teva's liability for its infringing sales of generic Prilosec for a three-year period beginning in September 2004. Plaintiffs have alleged that this effective forgiveness of liability amounted to a "payment" under *Actavis* and, in denying Defendants' motions to dismiss, this Court agreed. Memorandum and Order (Doc. 352) at 40-43 (Sept. 11, 2013). Nothing in Teva's motion gives the Court any reason to reconsider that ruling.

Under *Actavis*, the relevant issue is whether AstraZeneca sought "to induce [Teva] to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market." 133 S. Ct. at 2235. *See also id.* at 2234 (the payment "in effect amounts to a purchase by the patentee of the exclusive right to sell its product"). Teva argues that because *Actavis* immunizes entry-date settlements *without* a payment, and also immunizes

traditional damages-discount settlements, it must also immunize any agreement which *combines* an entry-date settlement with a damages-discount settlement. This is like arguing that because it is legal to ask a city official for a zoning variance, and also legal to contribute money to a city official, it must be legal to ask a city official for a zoning variance in exchange for a contribution of money. Sometimes two legal acts may be illegal when combined. *See, e.g., American Tobacco Co. v. United States*, 328 U.S. 781, 809 (1946) ("Acts done to give effect to the conspiracy may be in themselves wholly innocent acts").

Moreover, Plaintiffs *alleged* that the Teva and Dr. Reddy's settlement agreements combined an entry-date settlement of the *Nexium* case with a damages-discount settlement of the *Prilosec* and *Accolate* cases, respectively. Teva's interpretation of *Actavis* was just as applicable at the motion-to-dismiss stage as at the summary-judgment stage. The Court necessarily rejected Teva's legal argument when it found that Plaintiffs had stated a claim for relief under *Actavis*. Memorandum and Order (Doc. 352) at 40 (noting that elimination of Teva's and Dr. Reddy's' contingent liabilities for selling Prilosec and Accolate, respectively, were "entirely disconnected from AstraZeneca's earlier *Nexium-related* suits against these parties") (Sept. 11, 2013) (emphasis in original).

Teva's argument would undermine the antitrust policies adopted by the Court in *Actavis* and leave a substantial hole in antitrust enforcement. Under Teva's interpretation of *Actavis*, a branded manufacturer would be free to pay a generic competitor to delay its entry into the market so long as it did so by settling an unrelated case on terms favorable to the generic. Given the relatively small number of branded and generic manufacturers, and the ubiquity of patent litigation between them, it is almost inevitable that the parties to a Hatch-Waxman case will have other cases pending between them that can be settled. It is easy to imagine

hypotheticals in which a branded manufacturer settles a case worth hundreds of millions of dollars for a nominal payment and thereby induces a generic to delay its launch of an unrelated drug. A *per se* rule allowing such agreements would permit the very anticompetitive harm that *Actavis* seeks to avoid. *See* A. Edlin, S. Hemphill, H. Hovenkamp & C. Shapiro, *Activating* Actavis, ANTITRUST, Fall 2013, at 16, 18 (a reverse payment under *Actavis* "could include forgiving a debt owed by the claimed infringer to the patent holder," and the debt "may include patent infringement damages").

II. Plaintiffs Are Not Required to Prove That the Prilosec Settlement Was a Sham

Starting from the invalid premise that a reverse-payment settlement which combines an entry-date settlement with a damages-discount settlement cannot violate the antitrust laws under *Actavis*, Teva then creates an exception to that rule in cases where the damages-discount settlement is a "sham." Just as there is nothing in *Actavis* that supports the rule, there is also nothing in *Actavis* that supports the exception.

As this Court recognized in its opinion denying Defendants' motions to dismiss, *Actavis* requires only a *payment*, and the payment may be either monetary or non-monetary. Memorandum and Order (Doc. 352) at 42-43 (Sept. 11, 2013). It is self-evident (and the Court has held) that a branded manufacturer can pay a generic competitor by settling an unrelated lawsuit on terms that are favorable to the generic (*i.e.*, terms that it would not offer but for the contemporaneous agreed-upon delay in generic entry). *See Activating* Actavis at 18; *cf. Jang v. Boston Scientific Scimed, Inc.*, 729 F.3d 357, 363 (3d Cir. 2013) ("A cash offset [*i.e.*, cancellation of a debt] is the functional equivalent of a cash payment. Instead of receiving a direct transfer from Cordis, BSC deducted the amount it would have received from the amount it owed Cordis for separate acts of infringement").

Plaintiffs are not required to prove that AstraZeneca's settlement of the Prilosec litigation was a "sham," but only that it amounted to a payment from AstraZeneca to Teva that "induce[d] [Teva] to abandon its claim" that the Nexium patents were invalid or not infringed. *Actavis*, 133 S. Ct. at 2235. As three well-known antitrust scholars explain in a recent article, the plaintiffs in a reverse-payment case after *Actavis* are merely required to convince the jury that the generic challenger received "a positive quantity" after valuing the consideration flowing to the challenger and any goods or services provided by the challenger to the patent holder (of which there were none here). *Activating* Actavis at 18. *See also* Leffler Rebuttal Report at 7, ¶ 12 ("From an economic perspective, whether there is an offsetting cost to the branded seller from providing a benefit to the generic seller is not of relevance. What matters is that the generic receives a perceived benefit and is therefore willing to accept a later entry date").[1]

Teva cites the Business Judgment Rule and argues that, under it, a court is "prohibit[ed] from assessing the merits of a company's business decisions." Doc. 601 at 10 n.1. But this ignores the fact that federal antitrust law, unlike state corporation law, is constantly assessing the "merits" of firms' business decisions—not to see whether they serve the interests of the firm's shareholders (they do), but to see whether they serve the interests of competition. Almost by definition, anticompetitive behavior increases a firm's profits and makes its shareholders better off, but is not for that reason beyond the reach of the antitrust laws. *See Actavis*, 133 S. Ct. at 2235 (in a reverse-payment settlement, "[t]he patentee and the challenger gain; the consumer loses"); *United States v. General Motors Corp.*, 384 U.S. 127, 142 (1966)

[1] The authors of *Activating* Actavis contend that this netting process should deduct the patent holder's "avoided litigation costs." On this point, Plaintiffs disagree. Avoided litigation costs reduce the patent holder's net cost of entering into the settlement but do not affect the economic benefit to the generic challenger. *See Activating* Actavis at 18 n.22 (authors' analysis assumes that the benefits to the claimed infringer are also costs to the patentee).

("It is of no consequence, for purposes of determining whether there has been a combination or conspiracy under § 1 of the Sherman Act, that each party acted in its own lawful interest"). The policy served by the Business Judgment Rule—giving corporate officers breathing room do to what they genuinely consider to be in their shareholders' interests without facing legal consequences—simply has nothing to do with the pro-competition policies underlying the antitrust laws.[2]

III. There is Evidence That Teva Received a Positive Quantity From the Prilosec Settlement

As explained above, the proper inquiry is simply whether Teva received a "positive quantity" from the elimination of its contingent liability for three years of selling generic omeprazole and thereby infringing AstraZeneca's patents in exchange for a payment of $9 million.[3] Plaintiffs are not required to prove that AstraZeneca would in fact have obtained a damage award against Teva (although this appears to be conceded), or the amount of such an award, but only that Teva received a net economic benefit from the elimination of this possibility that was likely worth more than $9 million. *See* Leffler Rebuttal Report at 7, 12 ("What matters is that the generic receives a perceived benefit and is therefore willing to accept a later entry date"). A reasonable jury could so find.

Whether Teva benefited from the Prilosec settlement is primarily a legal issue, and specifically an issue of patent law. To the extent that the Court permits expert testimony on that issue, Plaintiffs have offered the expert opinion of Professor Jay Thomas of Georgetown

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[2] Likewise, Teva's appeal to the policy favoring settlements (Doc. 601 at 12-13) misses the mark, since that policy was expressly rejected as a reason to uphold reverse-payment settlements in *Actavis*. *See* 133 S. Ct. at 2234.

[3] Because Teva's infringement was arguably willful, it was potentially liable for treble damages and attorney's fees. 35 U.S.C. § 284, 285.

Law School, a law professor and the author of a well-regarded treatise entitled *Pharmaceutical Patent Law*.[4] Professor Thomas opines in his expert report that Teva faced "significant liability" to AstraZeneca for sales of generic Prilosec and was able to eliminate this liability for a "far smaller amount." Teva does not dispute Professor Thomas's qualifications or competence. However, it argues that the Court should disregard Professor Thomas's opinion because (a) AstraZeneca was seeking a reasonably royalty rather than lost profits; and (b) Professor Thomas did not attempt to quantify precisely the royalty to which AstraZeneca might have been entitled under the applicable case law. Neither point is sound.

First, the premise that AstraZeneca had forever waived its right to recover lost profits is flawed. It is based on a statement in a letter to a Special Master appointed to oversee discovery and made to support AstraZeneca's argument that certain discovery was irrelevant. Such elections are not irrevocable. *See Wagner v. Allied Chem. Corp.*, 623 F. Supp. 1412, 1415 n.2 (D. Md. 1985) (election of remedies is not irrevocable until final judgment). By settling with AstraZeneca, Teva eliminated the possibility that AstraZeneca would change its position, agree to provide the discovery it had previously refused to provide and seek lost profits.

Second, Professor Thomas was not required to quantify Teva's potential liability in order to conclude that the settlement represented a net economic benefit to Teva. *See Allen v. Martin Surfacing*, 263 F.R.D. 47, 56-57 (D. Mass. 2009) (expert's failure to offer specific measurements of solvents used in gym floor and the decedent's exposure to those solvents went to the weight rather than the admissibility of his testimony). This is not the Prilosec patent case

[4] The Court has denied Defendants' motion to exclude Professor Thomas' testimony for purposes of deciding Defendants' summary judgment motions but has granted it without prejudice for purposes of trial. Doc. 720. As explained in Plaintiffs' motion for reconsideration, Professor Thomas' opinions relate to areas other than the merits of the Nexium patent litigation.

and the jury will not be asked to award a reasonable royalty (or any other measure of damages) to AstraZeneca. The jury will simply be asked whether Teva received a payment through its contemporaneous settlement of the Prilosec patent infringement case. Professor Thomas's opinion "fits" the facts of the case and, "if admitted, likely would assist the trier of fact to understand or determine a fact in issue." *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co., Inc.*, 161 F.3d 77, 81 (1st Cir. 1998). If Teva believes that Professor Thomas should have put a dollar figure on Teva's potential liability and compared it to the settlement payments, its remedy is cross-examination, not exclusion. *See Milward v. Acuity Specialty Products Group, Inc.*, 639 F.3d 11, 15 (1st Cir. 2011); *Brown v. Wal-Mart Stores, Inc.*, 402 F. Supp. 2d 303, 308 (D. Me. 2005) ("As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination").[5]

IV. Teva Received an Economic Benefit That it Could Not Have Obtained by Winning the Patent Litigation

One of the defining features of reverse-payment agreements emphasized by the Supreme Court in *Actavis* is that the generic competitor receives something it could not have achieved by prevailing in the patent litigation, since the competitor has no claim for damages

[5] Teva's reliance on the outcome of AstraZeneca's patent litigation against Andrx (Doc. 601 at 16 n.3) is entirely misplaced. First, the case against Andrx did not conclude until September 2013 and its outcome could not possibly have affected the settlement agreement negotiated between AstraZeneca and Teva in 2009 and 2010. Second, as Teva acknowledges, Andrx, unlike Teva, made no sales of generic Prilosec. And third, the reason that AstraZeneca recovered no damages from Andrx was that the district court granted Andrx's *Daubert* motion and excluded the testimony of AstraZeneca's damages expert, which led AstraZeneca to concede that judgment should be entered in Andrx's favor. Schoen Declaration, Ex. 15. Andrx's motion was based on controlling Federal Circuit precedent holding that a patentee cannot obtain both a damage award based on future sales and an injunction prohibiting those very same sales. *Astra Aktiebolag et al. v. Andrx Pharms.*, Case No. 1:99-cv-09887-DLC, Doc. 189 at 1 (citing *Innogenetics, N.V. v. Abbott Laboratories*, 512 F.3d 1363, 1380 (Fed. Cir. 2008)).

against the patent holder. *See Actavis*, 133 S. Ct. at 2231 ("The FTC alleges that in substance, the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market, even though the defendants did not have any claim that the plaintiff was liable to them for damages. That form of settlement is unusual"); *id*. at 2233 ("In reverse payment settlements, . . . a party with no claim for damages (something that is usually true of a paragraph IV litigation defendant) walks away with money simply so it will stay away from the patentee's market. That, we think, is something quite different [from a traditional damages-discount settlement]"). *See also* Federal Trade Commission Brief as *Amicus Curiae* (Doc. 264), *In re Effexor XR Antitrust Litigation*, Case No. 3:11-cv-5479 (D.N.J.), at 7-8 (Sept. 13, 2013) ("when the inducement to settle and defer market entry includes something that the alleged infringer could not get even if it prevailed in the patent litigation, 'that . . . is something quite different' and may raise antitrust concerns") (quoting *Actavis*, 133 S. Ct. at 2233). It is of course this "reverse" nature that gives reverse-payment agreements their name.

There is no doubt that the AstraZeneca/Teva settlement merits this description. The patent litigation brought against Teva was a traditional paragraph IV Hatch-Waxman case, and neither party asserted a claim for damages. Teva's declaratory judgment action against AstraZeneca asserting the invalidity or noninfringement of other Nexium patents likewise did not include any claim for damages. Under no circumstances could have a favorable outcome in either case have eliminated Teva's contingent liability to AstraZeneca for infringing sales of generic Prilosec. Thus, the settlement agreement between AstraZeneca and Teva deserves to be called a reverse-payment agreement and should be subject to scrutiny under *Actavis*.

CONCLUSION

For the reasons stated above, Teva's motion should be denied.

Dated: January 9, 2014

Respectfully submitted,

/s/ Scott E. Perwin

Scott E. Perwin (pro hac vice)
Lauren C. Ravkind (pro hac vice)
Anna T. Neill (pro hac vice)
KENNY NACHWALTER P.A.
1100 Miami Center
201 South Biscayne Boulevard
Miami, FL 33131
Telephone: (305) 373-1000
sperwin@knpa.com
aneill@knpa.com
Attorneys for *Walgreen* Plaintiffs

Bernard D. Marcus
Moira Cain-Mannix
Brian C. Hill
Erin Gibson Allen
MARCUS & SHAPIRA LLP
One Oxford Centre, 35th Floor
Pittsburgh, PA 15219
Telephone: (412) 338-3344
E-mail: bdm@marcus-shapira.com
E-mail: cain-mannix@marcus-shapira.com
E-mail: hill@marcus-shapira.com
E-mail: jdm@marcus-shapira.com
Attorneys for Giant Eagle, Inc.

Barry L. Refsin
HANGLEY ARONCHICK SEGAL PUDLIN & SCHILLER
One Logan Square, 27th Floor
Philadelphia, PA 19103
Tel: (215) 568-6200
E-mail: brefsin@hangley.com

Monica L. Rebuck
HANGLEY ARONCHICK SEGAL PUDLIN & SCHILLER
4400 Deer Path Road, Suite 200
Harrisburg, PA 17110
Tel: (717) 364-1007
E-mail: mrebuck@hangley.com
Attorneys for *Rite Aid* Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that this document was electronically filed and served using the Court's ECF system on January 9, 2014.

/s/ Scott E. Perwin
Scott E. Perwin